Document Reference:PH-DOC-164Document Issue Number:01Document Issue Date:09/10/2019Page 1 of 109/10/2019



## **EU Declaration of Conformity**

Manufacturer:	Polyco Healthline Ltd.
Manufacturer's Address:	South Fen Road, Bourne, Lincolnshire, PE10 0DN, UK.
Product Brand:	Polyco
Product Description:	Optima (Yellow, Red, Pink, Green, Blue)
Product Codes:	02Y, 13R, 22P, 32G, 42B
PPE Category:	Category III

## It is declared that the above product:

is in conformity with the provisions of Regulation (EU) 2016/425 on personal protective equipment and with National Standards transposing harmonised standards EN ISO 374-1:2016, EN ISO 374-5:2016, EN 388:2016 and EN 420:2003+A1:2009.

Standard	Performance Levels	
BS EN 388:2016	1010X	
EN ISO 374-1:2016	KLMNPST	
EN ISO 374-5:2016	Protection Against Bacteria & Fungi	Protection Against Viruses
	Pass	N/A

is identical to the personal protective equipment which is the subject of EU Type-Examination Certificate number 0321/10438-01/E01-01, issued by SATRA Technology Centre, Wyndham Way, Telford Way, Kettering, Northamptonshire, NN16 8SD, UK (Notified Body number 0321), according to Annex V (Module B) of Regulation (EU) 2016/425.

is subject to the conformity assessment procedure Module D set out in Annex VII of Regulation (EU) 2016/425, under the surveillance of the notified body SGS Fimko Oy, P. O. Box 30 (Särkiniementie 3), 00211 Helsinki, Finland (Notified Body No. 0598).

This EU declaration of conformity is issued under the sole responsibility of the manufacturer, Polyco Healthline Ltd.

Signed for and on behalf of: Place and date of issue:	Polyco Healthline Ltd Bourne, 9 <sup>th</sup> October 2019
Name and role:	David Langridge, Laboratory and Technical Manager
Signature:	D Largridge
Expiry Date:	14 <sup>st</sup> May 2023
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